UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

VDP PATENT, LLC, Plaintiff, -against- WELCH ALLYN HOLDINGS, INC., et al., Defendants.	06 Civ. 5821 (GEL) **OPINION AND ORDER**

Michael B. Weiss, Cahill Gordon & Reindel LLP, New York, NY, for plaintiff.

Douglas J. Nash and John D. Cook, Hiscock & Barclay, LLP, Syracuse, NY, for defendants.

GERARD E. LYNCH, District Judge:

Plaintiff VDP Patent, LLC, ("VDP") owns a patented method to remove cerumen – earwax – from the ear canal, U.S. Patent No. 5,944,711 (the "'711 patent").[1] VDP accuses

[1] Cerumen is a "natural by-product of the ear canal" that "lubricates the skin lining in the ear canal, acts as a water repellant, and entraps dust, hair follicles, and foreign bodies." (Supplemental Declaration of Michael B. Weiss, dated March 14, 2008 ("Supp. Weiss. Decl."), Ex. 12, at 18.) Cerumen also protects the ear from infection. See WebMD.com, Ear Wax: An Overview, http://www.webmd.com/a-to-z-guides/earwax-topic-overview (last visited June 23, 2008); Chai, et al., Bactericidal Activity of Cerumen, 18 Antimicrobial Agents and Chemotherapy 638, 638-641 (1980). Although cerumen plays a beneficial role in the healthy functioning of the ear, in some instances earwax buildup becomes problematic, and earwax can "form[] a plug in the [ear canal] that can cause significant hearing loss" (Supp. Weiss Decl. Ex. 12, at 18), or become impacted against the ear drum, causing persistent ringing in the ears or vertigo. See WebMD.com, Ear Wax: An Overview. Some tools for removing cerumen, like ear picks and cotton swabs, may prove counterproductive (by pushing the wax farther down the ear canal or compacting the wax against the ear canal instead of removing it) or dangerous (by puncturing or otherwise damaging the eardrum). See WebMD.com, Ear Wax: Home Treatment, http://www.webmd.com/a-to-z-guides/earwax-home-treatment (last visited June 23, 2008). Water irrigation procedures can be one safe method to dislodge and remove such wax, although

defendants Welch Allyn Holdings, Inc., d/b/a Welch Allyn, Inc., ("Welch Allyn") a manufacturer of medical equipment, and Harold Ellis Drugs and Surgicals, Inc., a distributor of Welch Allyn's products, of selling an ear-washing system that infringes the '711 patent.

In a previous round of briefing, defendants moved for partial summary judgment on two grounds: first, that their device does not literally infringe the '711 patent, and second, that their device does not infringe plaintiff's patent under the doctrine of equivalents. By opinion and order dated June 28, 2007, this Court accepted the first argument and rejected the second. See VDP Patent, LLC v. Welch Allyn Holdings, Inc., No. 06 Civ. 5821, 2007 WL 1856516, at *1 (S.D.N.Y. June 28, 2007). The Court construed the term "otoscope" as used in the '711 patent's single claim, holding that an otoscope is not simply an *access* device but a *viewing* device as well, and that, in the context of the patent, the term denotes an instrument incorporating a light and lens, used for visual examination of the inner ear. Id. at *3-9. On that basis, the Court granted defendants partial summary judgment on the grounds that their device, which has neither a light nor a lens, does not literally infringe plaintiff's patent. However, the Court rejected defendants' motion for summary judgment that their device does not infringe plaintiff's patent under the doctrine of equivalents, noting that the issue "presents a question of fact that should not be determined until, at the earliest, after the parties have had an opportunity for further discovery." Id. at *13.

In its 2007 opinion, the Court construed only one element of the claim – otoscope – noting that "the parties may require a further opportunity to argue in detail the construction of

---

not all water delivery devices are appropriate or safe for cerumen removal. See WebMD.com, Ear Wax: Home Treatment).

other aspects of the claim." Id. at *3. Although the parties stipulate to the meaning of some elements of the '711 patent's claim (see Joint Claim Construction Statement, dated February 19, 2008), they disagree on the meaning of others, and now cross-move for the Court to resolve those disputes. Defendants also move for a finding that the patent is invalid as a matter of law because one particular element – "cylindrical shape in cross[-]section" – is indefinite.

The various elements at issue are properly construed as set forth below. Because defendants have failed to demonstrate by clear and convincing evidence that "cylindrical shape in cross[-]section" is indefinite, their motion for summary judgment of invalidity must be denied.

BACKGROUND

The background of this case is set forth in more detail in the Court's previous opinion and order. See 2007 WL 1856516, at *1-2. The final '711 patent contains only one claim:

> A method of irrigating a pat[i]ent's ear using an otoscope of a type having an operating mode of flushing cerumen therefrom with body temperature water, said method comprising the steps of [providing an otoscope,][2] configurating a tip of said otoscope in a cylindrical shape in cross[-]section and of a selected outside diameter, selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal, inserting said tip into said ear canal, establishing at a site of engagement of said different diameters of said tip and said ear canal opening a friction fit obviating fluid leakage externally of said site, providing a source of body temperature water and a return sump therefore, and continuously flowing said body temperature water from said source into and removing water and cerumen from said ear of said patient for return to said sump through said tip until the removal of cerumen is completed, whereby a maintained said fluid leakage seal during

[2] The parties agree that this bracketed phrase should appear in the claim and that it was erroneously omitted by the U.S. Patent and Trademark Office ("PTO") from the printed version of the Patent. VDP Patent, 2007 WL 1856516, at *1 n.1.

said continuous flowing of said body temperature water obviates a splattering of said patient.

('711 Patent, col. 4.)

DISCUSSION

I. Legal Standards

A. Claim Construction

Interpretation of a patent claim, which defines a patentee's rights, is a matter of law reserved entirely for the court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). "Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997).

1. Intrinsic Evidence

In construing a patent claim, courts must first examine the intrinsic evidence of record: the claim, specification, and prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The Court's task is to construe the meaning of a disputed term as it is used in the claim. Words in a claim are "generally given their ordinary and customary meaning," although an inventor "may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Id. (citations omitted). Therefore, intrinsic evidence is the "most significant source of the legally operative meaning of disputed claim language." Id. at 1582. In interpreting the terms of a claim, the first place to look is the language of the claim itself, as "the claims themselves provide substantial guidance as to the

meaning of particular claim terms." Phillips v. AWH Corp., 415 F.3d 1307, 1314 (Fed. Cir. 2005) (en banc) (citation and internal quotation marks omitted). "[T]he context of the surrounding words of the claim" can be "highly instructive," and "must be considered in determining the ordinary and customary meaning of those terms." Id. Furthermore, since "claim terms are normally used consistently throughout the patent," the usage of a term in one part of a claim may "illuminate the meaning of the same term" in other parts of the claim. Id. (citations omitted).

As claims are "part of a fully integrated written instrument [citation omitted] consisting principally of a specification that concludes with the claims," id. at 1315 (citation and internal quotation marks omitted), the specification is "always highly relevant" and "[u]sually . . . dispositive," Vitronics, 90 F.3d at 1582. The specification is "the single best guide to the meaning of a disputed term." Id. The Patent Act requires that the specification describe the claimed invention in "full, clear, concise, and exact terms," 35 U.S.C. § 112 ¶ 1, thereby emphasizing the importance of the specification in claim construction, Phillips, 415 F.3d at 1316. "[T]he inventor's intention, as expressed in the specification, is . . . dispositive." Id. (citation omitted).

The prosecution history "provides evidence of how the [Patent and Trademark Office, ("PTO")] and the inventor understood the patent." Phillips, 415 F.3d at 1317 (citation omitted). However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id.

2. Extrinsic Evidence

A court may also consider, in its "sound discretion," evidence extrinsic to the patent, including expert and inventor testimony, dictionaries, and treatises. Phillips, 415 F.3d at 1319. However, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms," id. at 1318, and therefore "less significant than the intrinsic record in determining the legally operative meaning of the claim language." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (citation and internal quotation marks omitted).

Dictionaries, especially technical dictionaries, are "properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." Phillips, 415 F.3d at 1318. Although expert testimony "can be useful," "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court." Id. at 1318. Moreover, a court should discount testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history." Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998).

3. Ordinary and Customary Meaning

The terms of a claim "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13 (citations and internal quotation marks omitted). This inquiry provides an "objective baseline from which to begin claim interpretation." Id. at 1313 (citation omitted). Although in some cases this knowledge may be

specialized, in other cases the ordinary and customary meaning of a term "as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314 (citation omitted). As the Court has already noted, "[t]he question is not the inventor's private or subjective intention, but the meaning that would be given his words by a person skilled in the art in the context of the patent." VDP Patent, 2007 WL 1856516, at *3.

B. Invalidity for Indefiniteness

Once issued by the PTO, "[a] patent shall be presumed valid." 35 U.S.C. § 282. However, the presumption is not conclusive, and a party accused of infringing a patent may assert as a defense that the patent or claim at issue is invalid. Id. § 282(3). "The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed. Cir. 1986) (citations omitted); see also 35 U.S.C. § 282 ¶ 1.

A patent or claim may be invalid if the patent owner failed to provide a proper specification, 35 U.S.C. § 282(3), one that "particularly points out and distinctly claims the subject matter the applicant regards as his invention," id. § 112 ¶ 2. This "requirement of claim definiteness . . . assures that claims in a patent are sufficiently precise to permit a potential competitor to determine whether or not he is infringing." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342 (Fed. Cir. 2003) (citation and internal quotation marks omitted). Since a claim "delineate[s] the patentee's right to exclude, . . . the scope of the claim[] [must] be sufficiently definite to inform the public of the bounds of the protected invention. . . .

Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008). "[T]he primary purpose of the requirement [of claim definiteness] is 'to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights.'" Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996), quoting Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369 (1938).

The standard of indefiniteness is "somewhat high," and "a claim is indefinite under § 112 ¶ 2 if it is insolubly ambiguous, and no narrowing construction can properly be adopted." Amgen, 314 F.3d at 1342. On the other hand, the "statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise." United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942).

Claims are not indefinite "merely because they present a difficult task of claim construction." Halliburton, 514 F.3d at 1249. "Proof of indefiniteness requires . . . an exacting standard," but is nonetheless met "where an accused infringer shows by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." Id. 1249-50; Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998); Marley Mouldings v. Mikron Indus., 417 F.3d 1356, 1359 (Fed. Cir. 2005). "When claims are amenable to more than one construction, they should when reasonably possible be interpreted so as to preserve their validity." Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996). Courts normally abide by a "principal of

preserving patent validity whenever possible." Affymetrix, Inc. v. PE Corp., 306 F. Supp. 2d 363, 378 (S.D.N.Y. 2004). By finding claims "indefinite only after reasonable efforts at claim construction prove futile," courts "accord respect to the statutory presumption of patent validity" and "protect the inventive contributions of patentees, even when the drafting of their patents has been less than ideal." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

"[D]etermination whether a claim is sufficiently definite[] is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1377 (Fed. Cir. 2000) (citation and internal quotation marks omitted); Halliburton, 514 F.3d at 1249; Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1344 (Fed. Cir. 2002); Exxon, 265 F.3d at 1376. Therefore, "[i]n the face of an allegation of indefiniteness, general principles of claim construction apply." Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1348 (Fed. Cir. 2005) (citation omitted). "[O]nce the patent issues, the claims and written description must be viewed objectively," Solomon, 216 F.3d at 1380, and a court will "typically limit its inquiry to the way one of skill in the art would interpret the claims in view of the written description portion of the specification," id. at 1378. As in the context of normal claim construction, "a court may consider or reject certain extrinsic evidence in resolving disputes en route to pronouncing the meaning of claim language." Exxon, 265 F.3d at 1376. To the extent that extrinsic evidence gives meaning to the understanding of a person of ordinary skill in the art, some situations may require a court to consider extrinsic evidence before invalidating a claim as indefinite. For example, in Verve, LLC v. Crane Cams, Inc., the Federal Circuit held that a district court invalidating a patent as indefinite "erred in law"

by "requiring that the intrinsic evidence . . . [be] the sole source of meaning of words that are used in a technologic context" and noted that "resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention." 311 F.3d 1116, 1119 (Fed. Cir. 2002). However, when construing a claim as definite or indefinite, just as in construing a claim in general, "the court is not crediting certain evidence over other evidence or making factual evidentiary findings. Rather, the court is looking to the extrinsic evidence to assist in its construction of the written document." Exxon, 265 F.3d at 1376 (citations and internal quotation marks omitted). Therefore, "the issue of indefiniteness" normally does not turn on "underlying factual dispute[s]" that would preclude resolution "as a matter of law on summary judgment." Id.

II. Legal Standards Applied

A. Person of Ordinary Skill In the Art

As noted above, terms in the patent are to be construed as they would be understood by "a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13. The Federal Circuit has adopted a multi-factored test for determining the appropriate person of ordinary skill, in which a court "may . . . consider . . . (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." Daiichi Sankyo Co., Ltd. v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citations and internal quotation marks omitted). These factors "are not exhaustive but are merely a guide." Id.

In the previous round of briefings, since neither party addressed the issue, the Court "adopt[ed] for the purposes of resolving [the issues then before the Court] the vantage point of a person of ordinary skill in the 'field of invention' [citation omitted] that is named in the '711 patent itself: the field of 'ear irrigation procedure.'" 2007 WL 1856516, at *3 n.3, citing Phillips, 415 F.3d at 1313. Plaintiff now contests that conclusion, asserting that "the 'field of invention' and hence the requisite level of skill in the art, is that of a practicing otolaryngologist[3] who regularly direct[s] the removal of ear wax from the human ear." (Plaintiff's Claim Construction Memorandum ("P CC Mem.")[4] 6 n.3.) Defendants, in contrast, argue that the Court's prior assumption was essentially correct, proposing that the person of ordinary skill in the art is "a medical doctor, nurse, or other medical professional who, as part of his practice, routinely irrigates the ears of his patients." (D CC Opp. 2.) Thus defendants' definition "include[s], but is not limited to, an otolaryngologist." (Id.)[5]

It is not clear what, if anything, turns on the dispute. In principle, determining "the proficiency of the hypothetical person of ordinary skill in the art" is "essential" to evaluating

---

[3] Otolaryngology is "a medical specialty concerned especially with the ear, nose, and throat." (Supplemental Declaration of Douglas Nash, dated March 7, 2008 ("Supp. Nash Decl."), Ex. 1.) An otolaryngologist is sometimes referred to as an ear, nose, and throat, or ENT, doctor.

[4] Defendants' opposition to plaintiff's claim construction memorandum will be cited as "D CC Opp." and plaintiff's reply will be cited as "P CC Reply." Similarly, defendants' claim construction motion will be cited as "D CC Mem."; plaintiff's opposition will be cited as "P CC Opp."; and defendants' reply will be cited as "D CC Reply." Defendants' motion for summary judgment on the issue of invalidity will be cited as "D Invalidity Mem."; plaintiff's opposition will be cited as "P Invalidity Opp."; and defendants' reply will be cited as "D Invalidity Reply."

[5] Defendants' formulation describes the person of ordinary skill as a range of people having skill in the art in question, but the relevant perspective is that of one (albeit hypothetical composite) person.

whether a claim is indefinite and therefore invalid, AllVoice Computing PLC v. Nuance Commc'ns, Inc., 504 F.3d 1236, 1240 (Fed. Cir. 2007), just as it is essential to evaluating the proper construction of a claim. However, as a practical matter, it is unclear whether adopting the parties' differing understandings of the appropriate person of ordinary skill in the art affect any issue in dispute in this case, because under either party's proposed construction, the record contains barely any testimony from any person with any purported skill in the art at issue that is useful to the Court in determining how the ordinary artisan would construe any of the disputed terms.

Defendants proffer no testimony from any person purporting to be a person of any skill in the art in question. Plaintiff, for its part, submits testimony from practicing otolaryngologists. (See Supp. Weiss Decl. Ex. 2, Declaration of Joseph B. Nadol, dated March 5, 2008 ("Nadol Decl."); Ex. 3, Declaration of Jack Wazen, dated February 18, 2008 ("Wazen Decl."); Ex. 4, Declaration of Daniel Pender, dated February 18, 2008 ("Pender Decl.").) Otolaryngologists, as medical doctors specializing in problems associated with the ear, are undoubtedly persons skilled in the art under either parties' understanding.[6] The parties disagree about whether otolaryngologists constitute a subset or the entire set of persons of skill in the art at issue (and therefore whether otolaryngologists are persons of "ordinary" as opposed to above-average skill in the art at issue). Regardless of who is correct, the Court would nonetheless consider plaintiff's otolaryngologists' declarations as relevant to the claim construction issues to the

[6] Plaintiff's proposed experts' declarations do not clearly establish that the experts actually satisfy plaintiff's own definition, as these otolaryngologists do not specifically claim to "regularly direct the removal of ear wax from the human ear." As neither party makes any argument based on this omission, the Court will assume that it is implicit that such procedures form a normal part of the practice of an otolaryngologist.

extent that those declarations are more than simply "conclusory, unsupported assertions by experts as to the definition of a claim term." See Phillips, 415 F.3d at 1318. However, almost all of the potentially relevant testimony is conclusory and unsupported so as to be of no use to the Court in determining how a person of ordinary skill in the art would understand the term. (See Nadol Decl. ¶¶ 10-21; Wazen Decl. ¶¶ 8-14, 16-21; Pender Decl. ¶¶ 7-20.) Whether individuals other than otolaryngologists are skilled in the art is entirely theoretical where no such individual is proffered by either party;[7] similarly, whether otolaryngologists are people of ordinary or above-average skill in the art is largely theoretical where the record testimony submitted by otolaryngologists is largely useless.[8] Whoever the Court determines to be the person of ordinary skill in the art, it will be left largely to its own devices to determine how that person would interpret the disputed claims.

Against the possibility that the issue may recur in the case, it merits noting that defendants appear to have the better of the argument; otolaryngologists, undoubtedly persons of skill in the art, are persons of above-average or extraordinary rather than ordinary skill.

---

[7] Plaintiff proffers the testimony of others unquestionably unskilled in the art at issue. (See Supp. Weiss Decl. Ex. 5, Declaration of David Grier, dated March 12, 2008, ¶ 1 (professor and researcher in physics with no stated medical qualifications or experience); Ex. 6, Declaration of David Pine, dated March 7, 2008, ¶ 1 (same); Ex. 7, Declaration of Myron Amer, dated March 5, 2008, ("Amer Decl.") ¶ 1 (attorney with no stated medical qualifications or experience).) These declarations are little if any use to the Court in determining how a person of ordinary skill in the art would understand the patent at issue.

[8] For those claim construction issues addressed in this opinion (not including the motion for reconsideration issues, which are dealt with separately, see Section II(C)(5)), plaintiff proffers only one assertion that is not an entirely conclusory and unsupported definition of a claim term: Wazen's testimony that "body temperature water" is "routinely understood in the clinical setting [as] a temperature range that is sufficiently close to the range of normal body temperature, such that injury and discomfort to a patient may be prevented." Wazen Decl. ¶ 15.

Although the inventor of the device at issue is a specialist (an otolaryngologist), the problem the invention was trying to solve is fairly simple – to create a leak-free ear irrigation device to remove cerumen from the ear. Unlike an invention developed in part based on animal testing, a skill "traditionally outside the realm of a general practitioner or pediatrician," see Daiichi, 501 F.3d at 1257, this invention appears to have been developed from a general understanding of human anatomy, specifically of the ear canal, medical devices, and fluid dynamics. Although the person of ordinary skill in the art may indeed be a medical professional, it is far from clear that knowledge necessary to create ear irrigation devices is limited to specialists, or indeed to licensed medical doctors. Furthermore, many of the prior art solutions appear to rather crude mechanical devices. See U.S. Pat. No. 4,201,212 for "Surgical Apparatus for Use in Syringing A Patient's Ear" issued to Margaret E. Bradley on May 6, 1980; U.S. Pat. No. 4,206,756 for a "Jet Ear Irrigation System" issued to Murray Grossan on June 10, 1980; U.S. Pat. No. 5,395,357 for "Splatter-Free Irrigation Device" issued to Perry L. Weigel on Mar. 7, 1995. While designing a device that can successfully remove earwax via a sealed irrigation process without damaging the inner ear would require some specialized knowledge, both the general problem of earwax removal and general solution proposed by much of the prior art and the current device are readily understood by laypersons.

The claim itself mentions neither physicians in general, nor otolaryngologist in particular. However, the specification notes that, in the context of the preferred embodiment, the waste water produced by the procedure is "appropriately disposed of at the option of the physician." ('711 Patent, col. 3.) On this basis, plaintiff argues that the person of "ordinary skill" is an otolaryngologist. This argument is unpersuasive. First, the specification mentions only a

"physician," not an otolaryngologist (or any other specialist for that matter). Second, the specification does not explicitly require the involvement of a physician during the procedure, and although the "preferred embodiment" of the procedure includes a physician, the preferred embodiment does not limit the scope of the claim or the patent. Third, it is not clear that an artisan of ordinary skill would need to be licensed or authorized to operate ear irrigation devices in every conceivable jurisdiction to be skilled in the art of invention.[9]

Tellingly, the specification notes that one version of the prior art is operated "under the observation of a qualified physician *or the like*." ('711 Patent, col. 2, emphasis added.) Therefore, at least one version of the prior art was not necessarily operated by (or even under the supervision of) a physician, thereby implying that an individual skilled in the art at issue need not even be a physician, let alone an ENT specialist.[10] The specification confirms this conclusion by specifically noting that the "field of the invention" is "ear irrigation procedure." (Id. col. 1.) Therefore, in construing the claims at issue, this Court will continue to adopt the vantage point of a person of ordinary skill in the field of ear irrigation procedure.

---

[9] Neither party offers evidence regarding whether, in any or all states, the procedures contemplated by the patent would necessarily be performed by a licensed physician, as opposed to a nurse-practitioner, physician's assistant, or other medical professional, or whether, under standard medical protocols, such procedures are appropriately performed only by certified otolaryngologists, rather than general practitioners. Moreover, even if only licensed physicians, or even specialists, were authorized to perform earwax removal procedures using the patented device, it is hardly clear that other medical professionals or even non-medical experts would not have sufficient experience in the field of ear irrigation, combined with sufficient knowledge of anatomy, hydraulics, and medical devices, to be potential inventors of competing devices.

[10] Even one of plaintiff's own experts appears to believe that the person overseeing the procedure contemplated by the '711 patent need not even be a physician. (Nadol Decl. ¶ 19 (describing "the physician *or individual overseeing the procedure*" (emphasis added)).)

B. Claim Construction: Undisputed Terms

The parties have stipulated to the meaning of a number of claim terms:

1. "**flushing cerumen therefrom**" means the "[a]ction of the water removes the ear wax from the ear canal;"
2. "**comprising**" means "[i]ncluding, but not limited to;"
3. "**configurating**" means "[g]iving a form to;"
4. "**ear canal**" means "a tube inside the ear that extends from the pinna (the visible part of the ear that resides outside of the head) to the eardrum;"
5. "**inserting said tip into said ear canal**" means that "[t]he tip is placed inside the outermost opening of the ear canal;"
6. "**obviating fluid leakage externally of said site**" means that "[t]he friction fit prevents water from leaking out of the ear;"
7. "**return sump**" means "[a] place permitting waste water containing ear wax to be deposited;"
8. "**removing water and cerumen from said ear of said patient for return to said sump through said tip**" means that "[t]he waste water and ear wax are removed from the ear canal and placed in the return sump."

(See Joint Claim Construction Statement.) These elements need not be construed by this Court, as the parties have stipulated to their meaning. The stipulated meaning and they may be helpful in resolving other disputed elements of the claim, as the "context of the surrounding words of the claim . . . must be considered" in determining the meaning of disputed terms. Phillips, 415 F.3d at 1314 (citations and internal quotation marks omitted).

C. Claim Construction: Disputed Terms

1. "tip" & "cylindrical shape in cross[-]section"

> . . . configurating a **tip** of said otoscope **in a cylindrical shape in cross[-]section** and of a selected outside diameter, selecting a **tip** outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal, inserting said **tip** into said ear canal, establishing at a site of engagement of said different diameters of said **tip** and said ear canal opening a friction fit obviating fluid leakage externally of said site, providing a source of body temperature water and a return sump therefore, and continuously flowing said body temperature water from said source into and removing water and

> cerumen from said ear of said patient for return to said sump through said **tip** until the removal of cerumen is completed . . .

Defendants claim that "cylindrical shape in cross[-]section" in the '711 patent defies construction and is indefinite, rendering the patent invalid in its entirety. (D Invalidity Mem. 5.) Their argument is simple: the "tip" of the otoscope is a three-dimensional tapering cone, and it is a "geometric impossibility for the cross[-]section of a three-dimensional object (i.e., the tip) to itself be a three-dimensional object (i.e., a cylinder)." (Id. 9-10.) However simple, it simply fails, as the appropriate construction of the disputed language does not render the language indefinite.

First, a cross-section of the otoscope's tip, construed as the entire head of the device, and not merely its ultimate edge, need not by definition be two-dimensional and therefore not cylindrical. Although it may be a "geometric" impossibility for a cross-section of a three-dimensional object to be a three-dimensional object, it is not a practical impossibility. To a geometer, a cross-section may be "the intersection of . . . a body in 3-dimensional space with a plane," Wikipedia.com, Cross section (geometry), http://en.wikipedia.org/wiki/Cross_section_%28geometry%29 (last visited June 23, 2008), and thus by definition a two-dimensional form. But the person of ordinary skill in the art of ear irrigation (or even of otolaryngology) is not a mathematician or expert in plane geometry. In ordinary English, a cross-section may be a "slice" of an object, and any actual three-dimensional object physically sliced into a cross-section would still have three dimensions, no matter how thin the slice. A cross-section, in this sense, is "[t]he cutting of anything across; a section made by a plane cutting anything transversely." IV Oxford English Dictionary 59 (2d ed. 1989). The OED provides the exemplar sentence: "Five men were twenty days felling it, the object being to have it sawed into

cross-sections to be shipped eastward to Europe." Id. The tree cross-sections shipped to Europe undoubtedly had a three-dimensional existence, and indeed were no doubt roughly cylindrical in shape. In the context of the claim, the particular slice at issue (created by the plane of the opening of the ear canal "cutting" the larger, more irregularly shaped ear-piece transversely), would be cylindrical.

Second, it is not clear that the term "a cylindrical shape in cross[-]section" is necessarily construed as meaning "a form whose cross-section is cylindrical" rather that "a form that is a cross-section of a cylinder."[11] If the "tip" of the otoscope does not refer to the entire head or ear-piece of the device, but simply to the very tip or end of that ear-piece, the leading edge of the tip could be construed as planar, and thus, even if "cross[-]section" is construed in the strict geometric sense, there would be nothing absurd about the specification. So construed, the two-dimensional cross-sectional "tip" would be the very edge of the ear-piece, which, in the context of the claim, would be circular.[12]

The parties differ about which construction of "tip" is correct. Defendants point out that the schematization of the preferred embodiment generally designates the entire three-dimensional ear-piece that tapers to a small cylinder as the "tip." (See '711 Patent, col. 2 & Fig. 3, No. 50.) However, given the prosecution history, this appears most likely to be an unintended

---

[11] Put another way, the phrase can be understood refer to a two-dimensional object (the cross-section of a three-dimensional cylinder, the result of which is a two-dimensional object) as a three-dimensional object (the cross-section of some other object, the result of which is a cylinder).

[12] The object would be a hollow circle or disc, as the patent claims a tip with an "outside" and, by implication, inside diameter. ('711 Patent, col. 4.)

side-effect of incorporating the spacing and font-size required for the proper drafting of figures, as opposed to a deliberate designation of the entire conical ear-piece as the tip.[13]

Plaintiff argues, in contrast, that the entire ear-piece as described in the preferred embodiment could never equate with the "tip" described in the claim. In the claim itself, plaintiff contends, the "tip" must be a subsection of the ear-piece, as the claimed method requires the operator to "insert[] *said* tip *into* said ear canal." ('711 Patent, col. 4, emphasis added.) It would be impossible for the entire ear-piece to be inserted into the ear canal, as the tapered ear-piece is, at some point, necessarily larger than the ear canal (thereby facilitating the friction fit so critical to the invention).[14] As it must be *inserted* into the ear canal, the claimed "tip" is at least the very edge of the ear-piece, and at most that portion of the ear-piece that breaks the plane of the outermost opening of the ear canal. This argument, however, is not conclusive, either. It is entirely consonant with normal usage to speak of "inserting" a finger or cotton swab "into" the ear, meaning that some portion of the finder or swab enters the ear, and not that the entire finger or swab disappears inside the ear. Similarly, to state that the tip of the otoscope is inserted into

---

[13] In the initial figure that represents the preferred embodiment, the "tip" referred to that portion of the ear-piece that, when inserted, broke the plane of the outer portion of the ear canal. (See Supp. Weiss Decl. Ex. 8, 12/8/97 Application of Daniel Pender, Draft Fig. 3.) The examiner initially rejected patent application in part because the submitted drawings failed to comply with regulations requiring black and white drawings, lines, and letters of uniform thickness and definition, and numbers, letters, and reference characters at least .32 cm in height. (Id. 11/20/98 Office Action, Attachment to Paper No. 2.) The numbers designating the various parts of the device were apparently too small, and Pender resubmitted the drawing, making the number designations larger and adding more space between them. In this reformulation, the "tip" designation was moved further up the ear-piece. (Id. 12/16/98 Response to Office Action, Fig. 3.)

[14] As defendants have acknowledged, this means that "[t]he tip is placed inside the outermost opening of the ear canal." (Joint Claim Construction Statement 2.)

the ear canal does not imply that the "tip" can only mean that portion of the otoscope that actually enters the canal, rather than a larger entity whose point or leading edge (or, indeed, whose "tip") goes inside the canal.

The inventor surely could have been more precise when claiming a "tip" of a "cylindrical shape in cross[-]section," and surely could have been more careful in labeling the graphical representation of the preferred embodiment, especially since claim terms are "normally used consistently throughout the patent." Phillips, 415 F.3d at 1314 (citations omitted). However, in the context of this patented method, the description of the tip is far from "insolubly ambiguous," and is sufficiently clear to a person of ordinary skill in the art to put the world on notice of the scope of the patent. Amgen, 314 F.3d at 1342.

First, either interpretation of "tip" and "cylindrical shape in cross[-]section" is sufficient to defeat defendants' claim that the claim is meaningless or defies construction. Second, either reading conveys exactly the same meaning to the reader of ordinary skill in the art, and indeed to any competent reader of English. Whether the tip of the otoscope means the entire ear-piece or the leading edge of that piece, and whether the "cylinder/cross-section" language is read to mean a cylindrical, three-dimensional cross-section of the ear-piece or the two-dimensional shape described by a planar cross–section of the cylindrical tip, the concept of the invention is clear, and is the same. The device described has an ear-piece that tapers to a cylinder, the cross-section of which is physically another cylinder and whose edge is a circle or disc,[15] which has a diameter

[15] A cylinder in two-dimensional cross-section may create shapes other than a circle (or a disc). Depending upon the angle of the plane intersecting the three-dimensional cylinder, rectangles, squares, circles, ovals, or more irregular objects may result. However, given the context of the patented method, it is natural to interpret the "cross[-]section" described in the claim as that cross-section of the ear-piece formed by its intersection with the plane of the

large enough that, when the tip is inserted into the ear canal (which on any construction of "tip" means that the leading edge of the ear-piece actually enters the canal), the ear canal is closed.

The '711 patent must be presumed valid, and the phrase at issue conveys to the reader that the ultimate tip of the ear-piece is essentially the edge of a cylinder – a circular or cylindrical shape – that breaks the plane of the outer ear canal. The entire ear-piece tapers from one end to another, but the leading portion of that ear-piece is cylindrical, and therefore, unlike the fully tapered side of a cone, ends in a circle, not a point.[16]

Based on the claim and the specification, the phrase "cylindrical shape in cross[-] section," is not indefinite, but refers to the shape that would result from a cylinder "cut" in cross-section by the ear-piece's intersection with the plane of the outermost ear canal. Defendants move for summary judgment on the issue of invalidity solely on the ground that this phrase is indefinite. They have failed to demonstrate by clear and convincing evidence that the language of the claim is insolubly ambiguous, and their motion must fail.

---

opening of the outer ear-canal, thereby resulting in a circular or slightly ovular shape (that facilitates a friction fit and fluid-tight seal, as will be discussed later). In any event, defendants nowhere argue that the patent is indefinite or unclear on the basis that a cross-section of a cylinder may result in two-dimensional shapes other than circles or ovals, and a common understanding of a cross-section is the object formed by the plane cutting the object "transversely." IV Oxford English Dictionary 59.

[16] As the claim specifically notes, the tip, like the edge of a cylinder, and again unlike a cone, has an "outside diameter." ('711 Patent, col. 4.) In contrast, the fully tapered edge of a cone cannot have an "outside diameter," as it is itself a point.

2. "selected outside diameter" & "selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal"

> . . . configurating a tip of said otoscope in a cylindrical shape in cross section and of a **selected outside diameter**, **selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal**, inserting said tip into said ear canal, establishing at a site of engagement of said different diameters of said tip and said ear canal opening a friction fit obviating fluid leakage externally of said site . . .

The parties disagree not only about *what constitutes* the tip, but about *who selects* the tip for any given procedure. Plaintiff argues that patent claims a method involving a tip that could be of a standard size pre-selected by the manufacturer or designer and used for all patients. (P CC Mem. 13.) In contrast, defendants argue that the tip size may vary from patient to patient, and the method's practitioner must select the appropriate tip for the size and shape of the particular patient's ear canal. (See D CC Mem. 12.)

As a matter of claim structure, the action of "selecting" a tip is parallel to the action of "configurating" a tip. That "configurating," or configuring, the tip (the action by which the tip is created) is done by the manufacturer may suggest that the action of "selecting" the appropriate tip diameter is also done by the manufacturer. However, other parallel verbs in the claim describe actions not of the device's manufacturer but operator – "inserting" the tip into the ear canal and "establishing" a friction fit – suggesting that the parallel structure is at best ambiguous regarding who selects the tip. Moreover, that the step of tip-diameter selection is separate from the step of tip configuration suggests that the two processes are different. Had only one standard

tip been contemplated, only one step would be needed: that of "configurating a tip of said otoscope in a cylindrical shape in cross- section and of a selected outside diameter that is slightly oversized with respect to an anatomical opening" of the ear canal in question. But the steps are distinct in the claim, and the Court must conclude that they are distinct for a reason.

Other intrinsic evidence supports the conclusion that the device's operator selects a particular tip for a particular patient. The friction fit discussed in the method is created when the tip, whose outside diameter is slightly larger than the patient's ear canal, forms a seal with the ear canal, creates the vacuum to remove the water and debris from the ear, and prevents leakage during the procedure. By claiming a "selected" tip that must correspond to "a diameter of an anatomical opening of *said patient's* ear canal" by being "slightly oversized," ('711 Patent, col. 4, emphasis added), the claim strongly suggests that the patented method contemplates a device provided with multiple, changeable tips. Perhaps there is more variety in other human characteristics than in the ear canal. However, if the human ear canal were of a standard size capable of being sealed by a one-size-fits-all device, the claim would be expected to have defined the shape of the tip not in relation to "said patient's" ear canal, but in relation to a constant, such as "the diameter of the anatomical opening of a human ear canal," or as a specified standard size (e.g., "5 millimeters in diameter").

Extrinsic evidence strongly supports the view that ear canals come in various sizes and shapes. The inventor, himself a practicing otolaryngologist, has acknowledged that "[t]here's a wide variety [in the sizes and shapes of ear canals] in the human species," and that standard otoscope specula (or ear-pieces) come in a variety of sizes and diameters. (Supp. Weiss Decl.,

Ex. 10, Deposition of Daniel Joseph Pender, M.D., dated January 31, 2008, ("Pender Dep.") at 63-65.) As the inventor colorfully noted in his deposition, "[y]ou can see 300 pound football players with pinhole ears and you can see midgets with sewer pipes." (Id. at 65.)

It may be possible to design some standardized tip that could create a fluid-tight seal for ear canals of all shapes and sizes. However, the claim here specifically sizes the relevant tip diameter in relation to a particular patient's ear canal, as opposed to some other form of measurement, and calls for a fit formed by friction between the tip and the canal. Given the variety among human ear canals, as the inventor has admitted exists, a tip that is "slightly oversized" for an individual with a small ear canal may be slightly undersized for an individual with a large ear canal, just as a tip that is "slightly oversized" for an individual with a large ear canal may be substantially oversized for an individual with a small ear canal. Similarly, a tip that is more than "slightly oversized" in relation to a particular patient's canal may be unable to be "insert[ed]" into the ear canal. See note 14 above.

Therefore, read in light of the external evidence of substantial variation in the diameter of human ear canals, the claim necessarily anticipates variation in tip sizes for different patients. Plaintiff argues that it would be an "absurd interpretation to require that each tip be perfectly sized to fit only the patient whose ear the tip is being inserted into." (P CC Mem. 14.) However, this is a caricature of the proper interpretation of the claimed method. The claim does not require bespoke tips; all it requires is that the tip be "slightly" oversized with respect to any particular patient's ear canal. ('711 Patent, col. 4.) Since the variety between small and large ear canals can be measured in millimeters (Pender Dep. at 65 (noting that otoscope specula can

range from 2 to 6 millimeters in diameter)), and the term "slightly" is a relative term that itself embodies some flexibility, it is likely that a limited set of tips can be used for the vast majority of patients.[17]

Accordingly, defendants' interpretation of this disputed term is adopted.

3. "site of engagement of said different diameters of said tip and said ear canal opening"

> . . . selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal, inserting said tip into said ear canal, **establishing at a site of engagement of said different diameters of said tip and said ear**

[17] It may of course be possible for a device to form a friction fit, perfect or otherwise, via a uniform tip. The ear canal is somewhat flexible (Pender Dep. at 64 (noting that "the lateral part of the canal is soft tissue, cartilage, and skin [that] is somewhat moldable")), and although there is "wide variation" in the size of ear canals such that what may be slightly oversized in relation to one patient's ear canal is undersized in relation to another patient's ear canal, that variation appears to be a matter of millimeters (id. at 65 (noting that otoscope specula can range from 2 to 6 millimeters in diameter)). That the claim at issue contemplates variety in tips does not necessarily mean that some slightly different method (perhaps one that incorporates a standard tip and allows for a very small amount of fluid leakage) would be safe from a judgment of infringement under the doctrine of equivalents. A device that "performs substantially the same function in substantially the same way to obtain substantially the same result" as a patented device infringes under the doctrine of equivalents. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950) (citation and internal quotation marks omitted); see also Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1566 (Fed. Cir. 1996) (noting that infringement under the doctrine of equivalents will be found where "the differences between the accused product or process and the claimed invention are insubstantial" (citation and internal quotation marks omitted)). A patentee may claim those "insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 733 (2002). Whether an accused device infringes under the doctrine of equivalents is a question of fact, Abraxis Bioscience, Inc. v. Mayne Pharma (USA), Inc., 467 F.3d 1370, 1375, 1380 (Fed. Cir. 2006), to "be determined against the context of the patent, the prior art, and the particular circumstances of the case," Graver Tank, 339 U.S. at 609.

> **canal opening** a friction fit obviating fluid leakage externally of said site . . .

The parties disagree about the location of the "friction fit" and the precise site of engagement. Whereas defendants argue that the site of engagement occurs when the inner ear canal contacts the outer diameter of the cylindrical portion of the tip (much like a cork sealing a bottle) (see D CC Mem. 15), plaintiff argues that the site of engagement "cannot be limited . . . to the ear canal itself," and is a seal that is "in or essentially in the ear canal." (P CC Opp. 18-19.) Plaintiff thus contends that the site of engagement may be the outside diameter of the tip against the inner wall of the ear canal (as defendants argue), the very edge of the tip as it is pressed directly against the ear canal, or some combination thereof.

The claim unambiguously requires that the outside diameter of the tip be "slightly oversized" in relation to the "anatomical opening" of the ear canal, and the site of engagement be at "said ear canal opening." ('711 Patent, col. 4.) The claim also requires that the seal be made at the canal's "opening," and that the tip be "instert[ed] . . . into said ear canal." Id. Therefore, the tip is "placed inside the outermost opening of the ear canal." (Joint Claim Construction Statement 2.) The claim itself thus does not appear to require that the seal be primarily formed either by the very edge of the tip or by the tip's outside diameter. Instead, it appears to allow the seal to be made by either, or some combination of both. The specification supports the notion that the seal is made either inside or roughly inside the ear by drawing an analogy to "inserting a finger in the ear canal to muffle or render inaudible external noise." ('711 Patent, col. 3.) The seal formed by a finger over an ear canal could be partly on the outside and partly on the inside

of the canal – the basic point is that the seal is created roughly around the opening of the ear canal.

External evidence about the shape and composition of the ear canal supports the conclusion that the seal may vary according to the particular patient (and ear) at issue. First, there is a "wide variety" in the size and shape of ear canals. (Pender Dep. at 63.) Second, ear tissue is somewhat flexible. The inventor testified that "the lateral part of the canal is soft tissue, cartilage, and skin [that] is somewhat moldable." (Id. at 64.) Since the canal opening is "somewhat moldable," the tip may, with pressure, cause the skin at the opening of the canal to slightly expand and allow the tip to enter the canal. The tip may also, with pressure, push the skin tissue, and cause it to slightly collapse inward. In either case, like a finger to the ear, regardless of whether the seal is created primarily around the canal or primarily on the inside of the canal, the central point is that the tip is slightly oversized, and when pushed inward against the canal opening creates a fluid-tight seal. In the context of this claim, it appears equally probable that, when pushed against the ear canal opening, the tip depresses the tissue of the ear canal inwards (forming a seal with the very edge of the tip) or expands the tissue of the ear canal outwards (forming a seal with the outside diameter of the tip).

Thus, plaintiff's interpretation of the site of engagement is correct.

4. "friction fit obviating fluid leakage externally of said site . . . whereby a maintained said fluid leakage seal during said continuous flowing of said . . . water obviates a splattering of said patient"

> . . . selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal, inserting said tip into said ear canal, establishing at a site of

> engagement of said different diameters of said tip and said ear canal opening a **friction fit obviating fluid leakage externally of said site** . . . **whereby a maintained said fluid leakage seal during said continuous flowing of said body temperature water obviates a splattering of said patient**.

Defendants argue that the friction fit creates a water-tight seal. (D CC Mem. 16.) Plaintiff, on the other hand, insists that the friction fit need not "completely prevent[] fluid leakage," and instead suggests that a "small degree of leakage is permissible." (P CC Mem. 16.)

The language unambiguously claims a "fluid leakage seal" – i.e., a seal that "obviat[es] fluid leakage." ('711 Patent, col. 4.) To obviate is "to prevent by anticipatory measures," X Oxford English Dictionary 674, not to minimize or reduce. (See also Supp. Nash Decl. Ex. 10.) As the specification reiterates, one "object of the present invention [is] to perform the ear irrigation procedure under a *fluid-tight seal*." ('711 Patent, col. 1, emphasis added.)[18] A seal, as defendants note, is a "tight and perfect closure (as against the passage of gas or water)." (Supp. Nash Decl. Ex. 12.) Other common uses of the word only serve to emphasize that the purpose of a seal is to prevent something from passing from one side of the seal to another (e.g., a sealed document, sealed lips). See XIV Oxford English Dictionary 793. The intrinsic record could not

[18] The specification at one point notes that the invention "more effectively maintain[s] the patient splatter-free without using a waterproof apron" ('711 Patent, col. 1), thereby suggesting that the risk of splatter is not completely eliminated, and thus that some leakage may occur at some point. When the device is removed from the ear canal there may be some leakage from the tip, or some water that remains inside the canal may subsequently evacuate, splattering the patient. However, it is clear from both the specification and the claim that such leakage and splattering does not occur during the ear irrigation procedure, as the "fluid-tight seal" "prevent[s] splattering of the patient," and the irrigation procedure itself is performed under a "fluid leakage seal." (Id.)

be clearer: the method claims a seal (during the irrigation procedure) that eliminates and prevents – not merely reduces – the passage of fluid from one side of the seal to the other. This is completely consistent with the parties' stipulation that "obviating fluid leakage externally of said site" means that "[t]he friction fit prevents water from leaking out of the ear." (Joint Claim Construction Statement 2.) Accordingly, defendants' construction of this term is preferred.[19]

5. "otoscope of a type"

> A method of irrigating a pat[i]ent's ear using an **otoscope of a type** having an operating mode of flushing cerumen therefrom with body temperature water . . .

Plaintiff asks the Court to reconsider its prior ruling construing the term "otoscope" to necessarily include a light and lens. (P CC Mem. 9.) However, this motion for reconsideration is untimely by months, and is denied. The Court's order was entered on June 28, 2007, and by local rule, plaintiff had ten days to move for reconsideration. See S.D.N.Y. Local Civ. R. 6.3. Instead, plaintiff waited for more than seven months before it moved for reconsideration. Not only is plaintiff's motion untimely, but it fails to identify any matters or controlling decisions that the Court has overlooked or misinterpreted. Id. Plaintiff also points to no substantial new evidence that the Court overlooked. Instead, it simply rehashes and reformulates old arguments this Court has considered and rejected, and repackages facts that this Court has already evaluated.

---

[19] Whether some method producing only a small degree of leakage and ensuring that a patient stays dry during the irrigation would infringe the '711 patent is most appropriately addressed in the context of the doctrine of equivalents and determined on the particular facts of the particular allegedly infringing device. See note 17 above.

As "new" evidence, plaintiff presents a barrage of declarations. (See Pender Decl.; Wazen Decl.; Nadol Decl.; Amer Decl.) These declarations could have been presented in the prior briefing, or at the latest in a timely motion for reconsideration. At any rate, even had plaintiff timely submitted the declarations, its arguments would still lack merit. Plaintiff's papers provide no reason to reconsider the Court's prior ruling, which clearly held that "the intrinsic evidence *dictates* an interpretation of the disputed claim term, 'otoscope,'" as requiring a light and lens. VDP Patent, 2007 WL 1856516, at *4 (emphasis added); id. at *3 (noting that "intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language" (citations and internal quotation marks omitted)).

First, plaintiff proffers declarations of the inventor and the prosecuting patent attorney that he did not intend to limit the term "otoscope" by means of a light and lens. (Pender Decl., ¶ 6; Amer Decl., ¶ 10.) However, as this Court has already held, claim construction depends "not [on] the inventor's private or subjective intention, but [on] the meaning that would be given his words by a person skilled in the art in the context of the patent." VDP Patent, 2007 WL 1856516, at *3; accord Solomon, 216 F.3d at 1379 ("[W]hat the patentee subjectively intended his claim[] to mean is largely irrelevant to the claim's objective meaning and scope." (citation omitted)). In the context of claim construction, "inventor testimony . . . is entitled to little, if any, probative value," as such testimony is "obtained in the context of litigation" and is "often a self-serving, after-the-fact attempt to state what should have been part of his or her patent application." Solomon, 216 F.3d at 1379 (citations and internal quotation marks omitted). The

subjective understanding of the prosecuting patent attorney is no more probative than that of the inventor.

Second, plaintiff presents a revised declaration (Wazen Decl., ¶ 5) from a proposed expert whose opinion this Court has already thoroughly considered and rejected, see VDP Patent, 2007 WL 1856516, at *9.[20]

Finally, plaintiff presents the testimony of another otolaryngologist that "where an otoscope has not been fitted with a light or lens, such device must be considered an otoscope." (Nadol Decl., ¶ 8.) This testimony does nothing to change the analysis. The Court did not hold that no device without a light and lens could ever under any circumstances properly be considered an otoscope. In fact, the Court noted that early otoscopes did not incorporate a light and lens. 2007 WL 1856516, at *8. Instead, the Court merely held that the term otoscope, as understood in the context of the particular claim at issue (and from the vantage point of a person

---

[20] In its prior opinion, the Court noted that, "[w]hether deliberately or not, witness Wazen does not specifically state that he understands an otoscope, in the context of the '711 patent, not to enable visualization of the ear canal via light and lens." VDP Patent, 2007 WL 1856516, at *9 n.6. Wazen's revised declaration now specifically states that he understands the '711 patent to incorporate an otoscope "with and without a lens or light." (See Supp. Weiss Decl. Ex. 6, Wazen Decl., ¶ 5.) However, regardless of what Wazen thought or did not think, the Court has already held that:

> even if the Court were to deem the intrinsic evidence insufficient to support adopting defendants' construction of otoscope, which it does not, and even if plaintiff's witness were to be credited as a qualified expert, the testimony would be rejected as advancing a definition that contradicts the internal coherence of a patent that requires a means for visualizing earwax removal.

Id. at *9.

of ordinary skill in the art of ear irrigation procedure) referred to a device equipped with a light and lens. Id. at *4-9.

Plaintiff's motion for reconsideration is therefore denied, and "otoscope" is construed in this opinion as it was construed in the Court's previous opinion, as an instrument fitted with a light and lens and used to facilitate visual examination of the ear canal during the irrigation procedure. See 2007 WL 1856516, at *3-9.[21]

6. "continuous[ly] flowing . . . until the removal of cerumen is completed"

> . . . providing a source of body temperature water and a return sump therefore, and **continuously flowing** said body temperature water from said source into and removing water and cerumen from said ear of said patient for return to said sump through said tip **until the removal of cerumen is completed**, whereby a maintained said fluid leakage seal during said **continuous flowing** of said body temperature water obviates a splattering of said patient.

The parties dispute whether the method must remove the targeted cerumen in one uninterrupted procedure. (See D CC Mem. 18-19; P CC Mem.18-19.) The dispute centers on the meaning of the term "completed." Defendants argue that the method clearly claims a single, uninterrupted, procedure in which the water-tight seal is not broken until the targeted cerumen is removed. (D CC Opp. 22.) Plaintiff contends that "completed" means "until that particular

[21] The preferred embodiment of a method cannot limit the scope or reach of the method claimed. However, as the preferred embodiment itself incorporates a light and lens, it is consistent with the proposition that an otoscope, in the context of this patented method, must incorporate a light and a lens. (See '711 Patent, Figs. 2 & 3, Nos. 40 & 74.)

cycle of cerumen removal is finished," arguing that "[c]ompleted refers to the procedure, not the removal of . . . wax." (P CC Mem. 19.)

Plaintiff points to nothing in the claim or specification suggesting that the method occurs in cycles. In fact, the breaking of the fluid-tight seal, as would be required between these "cycles," runs the risk of splattering the patient, an outcome that this patented method has been designed to avoid (and that is the central claimed advance of the method over the prior art).[22] The Court has already concluded that a light and lens are necessary components of the method precisely because they allow the operator to inspect the ear canal without breaking the water-tight seal and thus visually determine that the cerumen is removed and the procedure is completed.

Moreover, plaintiff is quite mistaken in stating that "completed," as used in the claim, "refers to the procedure, not the removal of . . . wax" (P CC Mem. 19), as the claimed method

---

[22] The specification emphasizes the ability of the method to remove cerumen in one continuous procedure, all while maintaining a fluid-tight seal. One version of the prior art used a syringe as the "water-delivering device of choice." ('711 Patent, col. 1.) The method of removal of water through a syringe device presented an "inherent complication" – "[e]ach time that the syringe is removed there is . . . the loss of any fluid-tight seal and this results in leaking of any exiting flow of the irrigating or flushing warm water." (Id.) The specification notes that "[u]nderlying the present invention is the recognition that an operating mode which contemplates the use of a continuous warm water supply under pressure is one which obviates the removal of the ear-irrigating instrument prior to an observed completion of cerumen removal." (Id. col. 2) In the "operating mode of the . . . inventive otoscope instrument . . . there is no release of the seal between the otoscopic tip and the wall bounding the ear canal until the cerumen removal is completed." (Id.) And, as defendants note, if the claimed method incorporated a series of "'cycles' with the device removed at the completion of each cycle, as opposed to a single effort without periodic removal," then it would have difficulty overcoming what the inventor himself identified as "shortcomings of the prior art use of a syringe that resulted in the patient getting wet each time the device was removed." (D CC Reply 23.)

flatly contradicts that position by requiring that the water flows continuously "until *the removal of cerumen* is completed" ('711 Patent, col. 4, emphasis added). Here, "completed" unquestionably refers to the "removal" of cerumen. In ordinary usage, "complete" means "to bring to an end, finish (an action, performance, work, a distance, period of time, etc.)" and "completed" means "finished, made complete." III Oxford English Dictionary 612. Moreover, "removal" implies finality, as it is "the act of taking away entirely." XIII Oxford English Dictionary 601. The claimed method thus expressly anticipates breaking the fluid-tight seal only after the "removal" (the act of taking the targeted cerumen away in its entirety) has been "completed" (finished, made complete).

That the procedure must be "completed" before the fluid-tight seal is broken does not necessarily mean that all cerumen must be removed from the ear during the course of any given procedure. The patent claim does not foreclose the exercise of clinical judgment during the procedure. The claim's method is dedicated to "flushing cerumen []from" the ear canal, but nowhere does the claim explicitly require that all cerumen be removed from the canal for the desired cerumen "removal" to be completed. The extrinsic evidence supports such an interpretation. Cerumen is not necessarily bad for a patient, and may even be beneficial.[23] Only certain accumulations of cerumen are harmful, such as when it becomes a compacted plug that causes hearing loss, persistent ear-ringing, or vertigo. Once such a plug is removed, and the patient regains his hearing ability or balance, further cerumen removal may be unnecessary and

[23] See note 1 above.

even counterproductive. The claim leaves the extent and amount of targeted earwax to be removed to the clinical judgment of the professional conducting (or supervising) the irrigation, appropriate given that the method is a medical procedure.

Similarly, the claim does not foreclose all possible interruptions in the procedure. In particular circumstances, there may be a need to interrupt a procedure for any number of clinical reasons. But the patented method undoubtedly claims the *capacity* to remove cerumen in one uninterrupted procedure. Therefore, the potential need to interrupt any given irrigation procedure for reasons specific to the clinical situation has nothing to do with any limitation of the method in maintaining a continuous flow of water in and out of the ear through a water-tight seal, and provides no reason to construe the claim as meaning anything other than what it clearly states: that the method contemplates a continuous uninterrupted procedure in which the seal is not broken until the targeted cerumen has been completely removed.[24]

7. "body temperature water"

> . . . providing a source of **body temperature water** and a return sump therefore, and continuously flowing said **body temperature water** from said source into and removing water and cerumen from said ear of said patient for return to said sump through said tip until the removal of cerumen is completed, whereby a maintained said fluid leakage seal during said continuous flowing of said **body temperature water** obviates a splattering of said patient.

---

[24] That the patent claims an integrated procedure does not necessarily insulate from a judgment of infringement a method that has the *capacity* to remove the cerumen in one complete and integrated procedure, but nonetheless adopts some superficial modification. For example, an infringer could not avoid liability by adopting the claimed method and incorporating the step of taking a coffee-break in the middle of the procedure. However, this is an issue more appropriately addressed in the context of the doctrine of equivalents. See note 17 above.

Defendants argue that this term means "water that is approximately 98.6 degrees Fahrenheit or 37.0 degrees Celsius." (D CC Mem. 10.) Plaintiff, in turn, proposes that the term describes water within "a range of temperature sufficiently close to body temperature such that discomfort and injury are avoided when such water is introduced into the ear." (P CC Opp. 11.) Plaintiff's proposal is more consistent with the terms of the patent, the extrinsic evidence, and common sense.

The claim incorporates characteristics of the particular patient being treated in formulating certain aspects of the method. For example, the proper tip for the procedure must be sized in relation to "said patient's" ear canal. In contrast, the proper temperature claimed is not "said patient's body temperature," implying that the element "body temperature" is based on some standard other than the patient's particular body temperature at the particular time when the procedure is performed.[25] It does not necessarily follow, however, that the reference to "body temperature" invokes a specific temperature as calibrated according to the Fahrenheit or Celsius scales.

The claim refers to body temperature in general, and the specification strongly suggests that the descriptor is used loosely as opposed to with precision. The specification describes the

[25] The context and logic of the claim support this conclusion. That the tip properly conforms to the patient's ear canal so as to facilitate the friction fit and water-tight seal is central to the method's success in keeping the patient dry during the procedure. In contrast, defendants provide no reason why slight variations in the temperature of the water would impede the success of the procedure in any manner. It appears that the temperature of the water at issue has as much to do with the comfort of the patient during the irrigation procedure as the success of the irrigation procedure itself.

preferred embodiment as using a "warm water supply." ('711 Patent, col. 2.) Reading the term "body temperature water" as defendants propose would render the preferred embodiment potentially inconsistent with the claim itself (because warm water need not be 98.6 degrees Fahrenheit), but reading the term in a looser sense would harmonize the claimed element with the description in the specification. It is therefore unnecessary to look to extrinsic evidence to conclude that the term is used somewhat loosely. However, the extrinsic evidence also overwhelmingly supports plaintiff's position. Plaintiff cites to various treatises noting that, contrary to defendants' assertion, body temperature is more accurately described as a range rather than a precise degree. (See P CC Mem. 17 n.7.) Plaintiff also proffers the declaration of a physician in support of its interpretation. (See Wazen Decl. ¶ 15 (noting that the term is "routinely understood in the clinical setting[] [as] a temperature range that is sufficiently close to the range of normal body temperature, such that injury and discomfort to a patient may be prevented").) This declaration only confirms what is implicit in the language of the patent – that the temperature of the water need not be directly measured in relation to the particular patient's body temperature, or even to some idealized body temperature.

Body temperature varies among and within individuals – there is no one temperature that could conform to every person's body temperature at any given point in time – and defendants provide no reason why "body temperature" water must mimic the precise body temperature of the particular patient at the particular moment of the procedure, or fall into some specific range of variances around a rigid general standard. Experts and laypersons alike use the term in a more functional sense than defendants acknowledge. Like the term "room temperature," the term

"body temperature" conveys a certain temperature range by rough approximation. On the basis of both intrinsic and extrinsic evidence, the Court concludes that the element of providing "body temperature water" means water sufficiently close to the conventional normal body temperature of 98.6 degrees Fahrenheit so as not to cause injury or discomfort when such water is introduced into the ear.

CONCLUSION

For the reasons stated, the claim terms are properly construed as has been discussed, and defendants' motion for summary judgment on the issue of invalidity is denied.

Dated: New York, New York
June 24, 2008

GERARD E. LYNCH
United States District Judge